Stanley W. Parry, Esq.
Nevada Bar No. 1417
Edward Chang, Esq.
Nevada Bar No. 11783
BALLARD SPAHR LLP
100 North City Parkway, Suite 1750
Las Vegas, Nevada 89106-4617
Telephone: (702) 471-7000
Facsimile: (702) 471-7070
E-mail: parrys@ballardspahr.com
E-mail: change@ballardspahr.com

Stephen J. Kastenberg, Esq.
(admitted pro hac vice)
Jason A. Leckerman, Esq.
(admitted pro hac vice)
Jessica M. Anthony, Esq.
(admitted pro hac vice)
BALLARD SPAHR LLP
1735 Market Street, 51st Floor
Philadelphia, Pennsylvania 19103
Telephone: (215) 665-8500
Facsimile: (215) 864-8999
E-mail: kastenberg@ballardspahr.com
E-mail: leckermanj@ballardspahr.com
E-mail: anthonyj@ballardspahr.com

Attorneys for Defendant
GlaxoSmithKline LLC

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

THE VACCINE CENTER LLC, d/b/a THE VACCINE CENTER AND TRAVEL MEDICINE CLINIC, a Nevada limited liability company,

Plaintiff,

vs.

GLAXOSMITHKLINE LLC, a Delaware limited liability company; APEXUS, INC., a Delaware corporation; SOUTHERN NEVADA HEALTH DISTRICT; DOES I – X and ROE CORPORATIONS I – X, inclusive,

Defendants.

Case No. 2:12-cv-01849-JCM-NJK

DEFENDANT GLAXOSMITHKLINE'S REPLY IN FURTHER SUPPORT OF MOTION FOR SUMMARY JUDGMENT

(Oral Argument Requested)

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Local Rule 56-1, and the Scheduling Order entered June 3, 2014, Defendant GlaxoSmithKline LLC ("GSK"), by and through its undersigned counsel, submits the following reply memorandum in further support of its Motion for Summary Judgment (Docket No. 168).

REPLY MEMORANDUM OF POINTS AND AUTHORITIES

After receiving hundreds of pages of discovery, and pursuant to an agreed upon schedule, on June 16, 2014 The Vaccine Center ("plaintiff") filed an amended complaint to serve as the refined and focused template for its case and, specifically, for summary judgment briefing. Plaintiff's amended complaint, like its original, asserts claims based on GSK's discounted sale of vaccines to Southern Nevada Health District ("SNHD") through the 340B Prime Vendor Program, a program Apexus administers under the supervision and aegis of the federal government. Plaintiff alleges that the sales to SNHD amount to price discrimination, prohibited by the antitrust laws, specifically the Robinson-Patman Act. As agreed by the parties and approved by the Court, this initial round of summary judgment briefing has focused on two independently dispositive, threshold issues. The first issue is whether defendants' vaccine sales made through the federal government's Prime Vendor Program renders those sales immune from antitrust challenge. The second is whether the vaccination program of SNHD—a statutorily created, charitable public health entity—brings the vaccine sales within the "own use" exemption applicable to charitable institutions when the challenged products—vaccines—are being used to further the institution's mission.

Plaintiff's opposition brief offers no basis for denying summary judgment on either ground. In fact, plaintiff's main theme is just that foreshadowed by GSK: that the Prime Vendor Program has broadened beyond its "entire intent." (Pl. Mem. at 1-2.) But that beef is one that plaintiff, a for-profit entity ineligible for the program, must take up with the Health Resources and Services Administration ("HRSA").

The specific legal issues raised by plaintiff are no more apt. Its repeated refrain that Congress excluded vaccines from the "340B Program" and did not authorize inclusion of vaccines as a value added product is of no consequence. There is no dispute that vaccines are excluded from the 340B Drug Pricing Program. The sales plaintiff complains of are pursuant to the Prime Vendor Program, which is a separate, congressionally mandated, program, not subject to the same restrictions as the 340B Drug Pricing Program. As explained in GSK's opening memorandum and further below, the entire point of the Prime Vendor Program is to provide discounts extending ***beyond*** the reach of the 340B Drug Pricing Program. In furtherance of this objective, HRSA's Office of Pharmacy Affairs ***directed*** that the Prime Vendor Program include discounts on vaccines that would otherwise not be available.

Ignoring (but not disputing) this fact, plaintiff extends its diversionary tactics by relying on case law relating to a type of immunity not asserted here and trying to draw a false distinction between Apexus and GSK based on privity of contract. Instead, as plaintiff's counsel acknowledged at the hearing on defendants' motion to dismiss, it is Byers v. Intuit., Inc., 600 F.3d 286 (3d Cir. 2010), that set forth the relevant standard for the conduct-based immunity. (Docket No. 114, Tr. Sept. 12, 2013 Hearing on Mot. to Dismiss). None of plaintiff's efforts can save it from the fact that GSK, by selling vaccines to SNHD at discounted rates pursuant to the Prime Vendor Program, was acting with the endorsement of the federal government—pursuant to HRSA's direction that vaccines be included in the program—and is therefore immune from antitrust liability.

Bereft of persuasive defenses to GSK's assertion of conduct based immunity, plaintiff in its brief also refers to GSK sales to SNHD with terms or conditions outside of the Prime Vendor Program, including those through a federal Centers for Disease Control ("CDC") program. But plaintiff's whole claim is based on sales made under the Prime Vendor Program. Whether GSK or others are supposedly abusing the Prime Vendor Program by selling under terms or with conditions that violate the

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

Program—as plaintiff seems to assert—is again a concern to be taken up with the government, not here, and not through the antitrust laws. If plaintiff means that there are other sales to which it also somehow has a complaint, that is a claim not articulated or developed here, and which should be brought another day.

Plaintiff's argument with regards to the "own use" exemption to the Robinson-Patman Act is fundamentally flawed as well. GSK explained in its opening memorandum that, in accordance with the standard established by the Supreme Court and the Ninth Circuit, the provision of vaccines, particularly those at issue here, furthers SNHD's institutional mission of protecting and promoting "the health, the environment and well-being of Southern Nevada residents and visitors." (GSK Mot. at § III.B.2.) Rather than address GSK's argument head on, plaintiff attempts to circumvent binding precedent from DeModena v. Kaiser Foundation Health Plan, 743 F.2d 1388 (9th Cir. 1984), in order to apply the Supreme Court's holding in Abbott Laboratories v. Portland Retail Druggists Assoc., 425 U.S. 1 (1976), in the exact way the Ninth Circuit prohibits (and in a way that in any event misreads Abbott itself). But DeModena is binding on this Court and its application demonstrates why the own use exemption applies here.

I. ARGUMENT

A. Plaintiff's Immunity Arguments Do Not Address the Merits of GSK's Immunity Defense

Plaintiff makes three arguments opposing GSK's defense that its participation in the 340B Prime Vendor Program is immune from antitrust scrutiny: (i) sales by GSK to SNHD were made outside of the 340B Program; (ii) no federal regulation or statute ***requires*** drug manufacturers to discount vaccines; and (iii) GSK is not in privity with the federal government. (See Pl. Mem. at 16-25.) Each of plaintiff's arguments misses the mark entirely.

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

1. Plaintiff's Argument That Certain of GSK's Sales to the Health District Are Outside 340B Prime Vendor Program Is Irrelevant to Plaintiff's Claims.

Plaintiff's amended complaint is premised on the theory that vaccine sales made pursuant to the Prime Vendor Program constitute price discrimination under the Robinson-Patman Act and makes no mention of any alleged harm from sales outside of the program. As explained in detail in GSK's and Apexus's opening memoranda, the Prime Vendor Program is a congressionally enacted program administered by the HRSA under which drug manufacturers agree to provide vaccines, among other things, to eligible charitable and public health entities at discounted rates. (Apexus Mem. at § I; GSK Mem. at § II.) Acting pursuant to and in accordance with HRSA's policy governing the administration of the Prime Vendor Program, GSK's participation in the program is immune from antitrust scrutiny. Plaintiff now claims that GSK is not immune because "GSK's sale of vaccines was not part of the 340B Program," (Pl. Mem. at 18), and such sales are in "violation of [GSK's] contract with Apexus." (Id. at 2.) Plaintiff cannot, however, amend its claims or raise a new theory of its case for the first time in opposition to summary judgment. McNeely v. County of Sacramento, 344 Fed.Appx. 317 (9th Cir. 2009). To the extent it is now attempting to do so, these arguments have been waived.

Even after having the opportunity to amend its complaint, plaintiff continued to limit its claims to the 340B Program. (Docket No. 154.) At the time plaintiff filed its Amended Complaint, it had received, through discovery from GSK and SNHD, not only the contractual documents referenced in its summary judgment response but also the sales data for the four vaccines at issue sold by GSK to SNHD from 2006 through 2013. Yet the Amended Complaint does not revise plaintiff's singular focus on the 340B Program and makes no mention of any sales other than those made pursuant to the 340B Program. In any event, it is for Apexus, not The Vaccine Center, to assert a violation of its contract with GSK. To be sure, plaintiff may

complain to HRSA about such conduct as well, if it wishes. But, sales made outside of the 340B Prime Vendor Program are not relevant to this case.

2. Vaccine Sales Are Properly Included as Part of the Prime Vendor Program and Any Dispute That They Are Not Is an Issue for Plaintiff to Raise with HRSA

Despite its diversionary efforts, plaintiff cannot escape the stark reality that its grievance is really with the administration of the Prime Vendor Program by the federal government, not with GSK. HRSA's Office of Pharmacy Affairs directed that vaccines be included as part of the Prime Vendor Program. (See GSK Mot. at 8; Apexus Mot. at § IV.E.) From that point on, HRSA has continued to promote the inclusion of vaccines as value-added products as part of the program, including in reports to Congress and through its Request for Proposal for selecting a Prime Vendor. (See GSK Mot. at 8-9; Apexus Mot. at § IV.E.)

Plaintiff tries to avoid the misplaced nature of its lawsuit, as well as the undisputed fact that GSK's sale of vaccines under the Prime Vendor Program was in accordance with HRSA's directive to include vaccines in the program, by pointing to the exclusion of vaccines from the 340B Drug Pricing Program as somehow tainting GSK's and Apexus's conduct. But whether or not vaccines are part of the 340B Drug Pricing Program is irrelevant to the inquiry here and not a basis for antitrust litigation. As explained in detail in Apexus's and GSK's summary judgment motions, the Prime Vendor Program is distinct from the 340B Drug Pricing Program. Mandated by federal statute, the Prime Vendor Program is premised on the notion of providing discounts and services ***not*** already offered by the Drug Pricing Program. 42 U.S.C. § 256b(a)(8). Thus, by its very nature, the Prime Vendor Program is designed to reach beyond the discounts offered to covered entities as part of the Drug Pricing Program in order to "stretch scarce Federal resources as far as possible" by providing greater discounts on covered drugs and discounts on additional value added products. As explained *supra*, vaccines were added to the Prime Vendor Program with HRSA's consent and endorsement. And the contract between Apexus,

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

acting on behalf of HRSA as the Prime Vendor, and GSK covers vaccines—a fact plaintiff cannot and does not dispute. When a covered entity such as SNHD places an order for vaccines, GSK verifies that the entity is eligible to make the purchase based on a list of covered entities provided by Apexus.[1] If plaintiff disagrees with vaccines being sold in this manner, its complaint lies with the federal government, not the entities acting pursuant to the program's directives.[2]

Plaintiff in effect concedes that if vaccines are sold as part of the Prime Vendor Program at the federal government's direction, Defendants' conduct is immune. Plaintiff admits that it "does not dispute that Defendants may be immune from antitrust liability for their involvement in selling and purchasing covered outpatient drugs—as opposed to *vaccines*—at a price discount under the 340B Program." (Pl. Mem. at 17 n.11.) Plaintiff confirms that "Congress has explicitly authorized price discrimination" through its decision to establish parameters for the price at which outpatient drugs may be sold to covered entities (Id.) By extension, if the inclusion of vaccines at discounted prices is similarly authorized by the government, defendants' conduct is also immune.

With regards to the Prime Vendor Program, the federal government, acting through HRSA's Office of Pharmacy Affairs, directed the inclusion of vaccines. (See Apexus Mot. at § IV.E-F; GSK Mot. at § III.A.) Plaintiff's grievance that Congress excluded vaccines from the definition of "covered outpatient drugs" (Pl. Mem. at 17 n.11) applies to the 340B Drug Pricing Program. Plaintiff never grapples with the sale of vaccines as a part of the Prime Vendor Program. Conduct-based immunity

[1] See HRSA Office of Pharmacy Affairs, Covered Entity Search, available at http://opanet.hrsa.gov/opa/CESearch.aspx.

[2] To the extent plaintiff implies that GSK sales to SNHD outside of the 340B Prime Vendor Program somehow violate the terms of the contract between Apexus and GSK (see Pl. Mem. at 2), The Vaccine Center has no standing to enforce the terms of a contract of which it is neither a party nor an intended third party beneficiary. German Alliance Ins. v. Home Water Supply, 226 U.S. 220, 230 (1912).

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

does not require a statutory mandate but, as plaintiff also concedes, requires that "(1) the government agency is acting pursuant to a clearly defined policy or program; and (2) the private party is acting at the direction or consent of the government agency." (Pl. Mem. at 16 citing Byers, 600 F.3d at 295.) Extending plaintiff's own reasoning, if vaccines are properly included in the ***Prime Vendor Program*** at the government's direction—which they indisputably are—Defendants' involvement in selling and purchasing vaccines under the program is similarly immune.

3. Plaintiff Relies on an Unrelated Theory of Immunity

When addressing GSK's immunity defense directly, plaintiff relies extensively on the argument that the decision in Phonetele, Inc. v. Am. Tel. & Tel. Co., 664 F.2d 716 (9th Cir. 1981), does not support immunity because no statute or regulation requires GSK to discount vaccines. (Pl. Mem. at 19-22.) But Phonetele involves a different immunity ***not*** asserted by GSK. The defendants in Phonetele asserted immunity derived from the regulatory scheme imposed by the Communications Act of 1934 ("FCA") as implemented by the Federal Communications Commission ("FCC"). Phonetele, 664 F.2d at 727. This form of implied antitrust immunity is premised on either the pervasive regulation of an industry by an agency or the delegation of self-regulating authority. Id. at 726-29. Conduct-based immunity, instead, is focused on specific conduct expressly sanctioned by the federal government. Indeed, one of the distinctions between the type of immunity at issue in Phonetele and GSK's defense here is that the immunity enjoyed by regulated entities is without regard to whether the agency directs or approves the conduct at issue. Id. In contrast, conduct-based immunity is applicable here because HRSA has directed and endorses the sale of vaccines pursuant to the Prime Vendor Program. Accordingly, plaintiff's reliance on Phonetele is misplaced and has no bearing on the conduct-based immunity asserted by GSK.

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

4. Plaintiff's Privity Argument Is a Red Herring

Plaintiff's argument that, for immunity to apply, GSK must be in "privity with any federal agency" fares no better. As a threshold matter, privity is not a prerequisite to conduct-based immunity. In Name.Space, Inc. v. Network Solutions, Inc., the Second Circuit made clear that "mere status as a government contractor" was insufficient to confer immunity. 202 F.3d 573, 581 (2d Cir. 2000). Rather, the focus was on the ***conduct*** at issue. The Byers court made this very point in finding that "conformance" to IRS policy was the basis for immunity. Byers v. Intuit, Inc., 600 F.3d 286, 295 (3d Cir. 2010).

Moreover, there is no dispute that GSK has a contract with Apexus governing GSK's participation in the Prime Vendor Program. Apexus, as the Prime Vendor of the program, acts on behalf of HRSA, the unit of the federal Health and Human Services Department tasked with administering the program. That GSK's contract is with HRSA's program administrator rather than the agency itself is irrelevant when immunity considers the conduct of the parties. To find otherwise would produce the anomalous result that Apexus, but not GSK, is entitled to conduct-based immunity, even though Apexus is the federal proxy charged with implementing the Prime Vendor Program and the government endorses GSK's conduct pursuant to the program.

B. Plaintiff Ignores Binding Ninth Circuit Precedent for Applying the "Own Use" Exemption

The Court should award summary judgment for the independent reason that GSK's sales to SNHD are protected by the "own use" statutory exemption to the Robinson-Patman Act.

The Vaccine Center's response to this issue suffers from two fundamental problems. First, it misstates the legal standard for the "own use" exemption set forth by the Supreme Court in Abbott Laboratories v. Portland Retail Druggists Assoc., 425 U.S. 1 (1976). Second, it ignores the later, binding Ninth Circuit precedent

interpreting Abbott and further making clear the "own use" standard to be applied here. The Robinson-Patman Act does not reach purchases of supplies to "schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit" that are "for their own use." 15 U.S.C. § 13(c). In Abbott, the Court addressed whether ten enumerated activities of the hospital in that case qualified as "own use" and, as a result, were exempt from antitrust scrutiny. Id. Plaintiff tries to shoehorn the conduct at issue here into one of those ten categories—namely, prescriptions filled at a hospital pharmacy by a "walk in" customer not otherwise treated at the hospital. The Abbott Court held that this conduct was not for the plaintiff hospital's own use. Plaintiff here claims the same result by definition should be reached here. But the point of Abbott was in evaluating whether the challenged conduct fell within the charitable mission of a hospital—and indeed the specific hospital at issue there.

Not surprisingly, the Ninth Circuit, in DeModena v. Kaiser Foundation Health Plan, prohibits the precise exercise attempted by plaintiff, explaining:

> Appellants ask us to adopt the categorical rules set forth in Abbott Labs wholesale and apply them to this case. This suggestion, however, ignores the manner in which these rules were originally derived and would, if adopted, violate the spirit, if not the letter of the Supreme Court's decision.

743 F.2d 1388, 1393 (9th Cir. 1984). As the Ninth Circuit further explained, the Abbott Court "generated its categorical rules by first determining the basic institutional function of a non-profit, fee-for-service hospital and then deciding which sales fit within this institutional function." Id. Accordingly, the DeModena court instructs:

> to follow the true mandate of Abbott Labs, we should not simply adopt the categorical rules set forth in that decision, but should instead determine the basic institutional function of the [entity] and then decide which sales are in keeping with this function.

Id.

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

The Ninth Circuit's interpretation of how to apply Abbott is binding on this Court. Yet plaintiff ignores DeModena by focusing solely on the distinction between patients of a hospital and "walk in" customers of a pharmacy made by the Abbott Court. This distinction, while relevant when considering the institutional function of a hospital, is of no significance when considering the institutional function of a community health organization like SNHD. A proper application of the Ninth Circuit's mandate first identifies SNHD's institutional function and then considers what sales fit within that function, a task plaintiff disregards completely.

SNHD's mission, to promote and protect "the health, the environment and well-being of Southern Nevada residents and visitors," encompasses, among other things, the prevention and control of communicable diseases. Plaintiff does not dispute this. Nor does it dispute that this directive is served by SNHD's immunization program, as explained in detail in GSK's motion. (GSK Mot. at § III.B.2.) Moreover, this goal is not limited to "patients" or individuals in a contractual relationship with SNHD, as plaintiff suggests. Rather, the effective control and prevention of communicable disease (which undeniably improves the health of the community at large) goes hand-in-hand with improved access to vaccinations, including those used for travel. Indeed, plaintiff's suggestion that the provision of vaccines required for travel out of the country is "irrelevant" to the prevention of the spread of disease (Pl. Mem. at 22 n.13), defies logic. Individuals traveling to foreign countries, particularly locations with diseases not common to the United States, risk not only getting ill themselves but also carrying a disease back to their home and infecting others. This is precisely the reason why travel vaccines are a critical aspect of attaining the high vaccination rates needed for herd immunity, and thus furthering SNHD's mission.

Even setting aside that DeModena is binding precedent, this Court should still decline to adopt plaintiff's mechanical application of the categorical rules from Abbott. This Court should not conflate the Supreme Court's articulation of the test

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

for determining "own use" with its application of that test to one of the enumerated examples in the statute—the hospital setting. There is no dispute that SNHD is not a hospital but otherwise qualifies as a "charitable institution" for purposes of the NPIA. How the Abbott Court defined a hospital's institutional function, therefore, serves little purpose in determining whether the sales at issue here promote SNHD's mission. As explained above and in GSK's motion, providing vaccinations to the community in the manner done so by SNHD promotes the organization's mission of improving "the health, the environment and well-being of Southern Nevada residents and visitors." As a result, GSK's sales to SNHD qualify for the own use exemption from the Robinson-Patman Act.

II. CONCLUSION

For the reasons above, as well as those set forth in GSK's motion, GSK respectfully requests that this Court enter summary judgment in favor of GSK and against The Vaccine Center.

Dated: October 6, 2014.

By: /s/ Jessica M. Anthony

Stanley W. Parry, Esq.
Nevada Bar No. 1417
Edward Chang, Esq.
Nevada Bar No. 11783
BALLARD SPAHR LLP
100 North City Parkway, Suite 1750
Las Vegas, Nevada 89106
Telephone: (702) 471-7000

Stephen J. Kastenberg, Esq.
(admitted pro hac vice)
Jason A. Leckerman, Esq.
(admitted pro hac vice)
Jessica M. Anthony, Esq.
(admitted pro hac vice)
BALLARD SPAHR LLP
1735 Market Street, 51st Floor
Philadelphia, Pennsylvania 19103
Telephone: (215) 665-8500

Attorneys for Defendant GlaxoSmithKline LLC

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070

CERTIFICATE OF SERVICE

I certify that on October 6, 2014, a true copy of **Defendant GlaxoSmithKline's Reply in Further Support of Motion for Summary Judgment** was filed via the Court's CM/ECF System and electronically served by the Court on all parties in interest.

/s/ Sarah Walton
An employee of BALLARD SPAHR LLP

BALLARD SPAHR LLP
100 NORTH CITY PARKWAY, SUITE 1750
LAS VEGAS, NEVADA 89106
(702) 471-7000 FAX (702) 471-7070